510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
K041297

B. Purpose for Submission:
New device

C. Analyte:
Human hemoglobin

D. Type of Test:
Immunological test for the qualitative detection of monoclonal antibodies for human hemoglobin

E. Applicant:
Polymedco, Inc.

F. Proprietary and Established Names:
Poly stat OC Light FOBT Test

G. Regulatory Information:

1. Regulation section:
   21 CFR § 864.6550
2. Classification:
   Class II
3. Product Code:
   KHE-Reagent, Occult Blood
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The Poly stat OC Light FOB test is an immunological test intended for the detection of fecal occult blood in feces by professional laboratories and physician office labs. The test is useful for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal (GI) disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
2. Indication(s) for use:
   The OC Light test is recommended for use in 1) routine physical examinations, 2) monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding.
3. Special condition for use statement(s):
   None
4. Special instrument Requirements:
   None

I. Device Description:

The OC Light test kit consists of sampling bottles containing an extraction buffer and immunochromatographic test in strips in a screw cap bottle with desiccant.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Instant-View Fecal Occult Blood Rapid Test
1. Predicate K number(s):
   k021423
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Test Principle	Immunoassay lateral flow test strip system utilizing MAbs for the detection of human hemoglobin	Immunoassay lateral flow test strip system utilizing MAbs for the detection of human hemoglobin
Sample	Feces in an extraction buffer	Feces in an extraction buffer
Differences		
Item	**Device**	**Predicate**
Extraction Buffer	HEPES buffer	PBS Buffer
Test Device	Dipstick	Cassette and Dip-strip

K. Standard/Guidance Document Referenced (if applicable):

"Review Criteria for the Qualitative Assessment of Fecal Occult Blood In Vitro Diagnostic Devices"

L. Test Principle:

The Poly stat OC-Light FOB Test is an immunoassay utilizing two monoclonal antibodies (MAbs) to specifically detect the presence of human hemoglobin in feces. The dipstick test strip incorporates a membrane –immobilized murine anti-Hb capture MAb and a conjugated murine anti-hCG MAb. The procedural control zone contains an immobilized goat anti-mouse IgG-specific antibody. The sample end of the test strip is dipped in the fecal extract. The liquid fecal extract migrates by capillary action through the test strip. If the concentration of the hHb is at or above the cutoff it links the latex conjugate to the capture antibody in the patient test zone. The control zone antibody should bind the monoclonal antibody on the latex regardless of the presence of hHb. The buildup of latex particles in the zones leads to the development of visible blue bands.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility studies were conducted at three physican office labs (POLs), 100 human hemoglobin free stool extracts were collected and separated in five groups of twenty. Each group of specimens was spiked with a known level of human hemoglobin to result in the following concentrations; 0 ng/mL, 30 ng/mL, 50 ng/mL (at the cut-off), 62.5 ng/mL (just above the cut-off), and 2000 ng/mL (prozone). Twenty-four POL subjects of various degrees of educational backgrounds and experiences participated in the reproducibility studies conducted at three sites. The total number of determinations

of the OC Light FOB test at the POLs was 300. The results of the studies are presented in the table. The number of positive and negative results for each level of spiked hemoglobin concentration is presented. There was over 99.3% (298/300) agreement between the results obtained from the POL and the results obtained from the reference laboratory. The overall accuracy of the OC Light test by the POL users was 98.9% (189/191).

Reproducibility Studies by POL and Professional User

	Target Concentration of Hb in extracted feces in ng/mL				
	0	**30**	**50**	**62.5**	**2000**
Polymedco OC Light FOB Test (24 POL Subjects at a Total of 3 Sites)					
Positive reads	0	22	47	60	60
Negative reads	60	38	13	0	0
Total	60	60	60	60	60
Polymedco OC Light FOB Test (Professional User)					
Positive reads	0	23	48	60	60
Negative reads	60	37	12	0	0
Total	60	60	60	60	60
Alfa Scientific Test (Predicate Test by a Professional User)					
Positive reads	0	23	48	60	60
Negative reads	60	37	12	0	0
Total	60	60	60	60	60

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
Internal (Procedural) Control: Is built into the test strip and assures that the sample addition and migration through the test strip has occurred and that the control anti-mouse antibody and the reporter antibody are intact and functional.
External Control: Assures that the capture and conjugated antibodies are present and reactive. This control should be performed once per kit lot per operator.

d. Detection limit:
Not applicable

e. Analytical specificity:
Stool extract samples were spiked with hHb at five different concentrations: 0, 30, 50, 62.5, and 2000 ng/mL. Eight replicates of each concentration were prepared to total forty stool extraction samples. Samples were tested with three lots of the OC Light Dipstick and one lot of the predicate device. There was 100% agreement between the OC Light test and the predicate test at the concentrations well below and above the cutoff.

Animal hemoglobins and tissues

A performance study was completed to investigate the cross reactivity of other species of hemoglobin (HB) and tissue extracts on the OC Light dipstick and Alfa Instant View device (predicate). HB of bovine, equine, pig, rabbit, sheep, fish, chicken and goat origin ws added to the test device to determine the cross reactivity of the test with Hb of other species. Each Hb species was added to normal stool extracts at both 0 and 50 ng/mL human hemoglobin (hHb). The results were as expected. The negative results continued to be negative and the positive results continued to be positive after the addition of the animal hemoglobins. The study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish, chicken and goat and no cross reactivity was evident.

Human hemoglobin

A study was completed to investigate the performance of the OC Light dipstick and Alfa Instant View device (predicate) with abnormal blood samples. Two types of abnormal blood were tested (Thalassemia and Sickle Cell) and the results compared to Normal human hemoglobin (hHb). Stool extract samples were spiked with whole human blood (approximately 14.6 g/dL if hemoglobin) at four different concentrations: 0, 25, 50, and 150 ng/mL. The results were as expected. At the concentration of 0 and 25 ng/mL the OC Light test was negative and at the concentrations of 50 and 150 ng/mL the OC Light test was positive. The studies suggest that there are no false negative issues measuring hemoglobin variants found in Thalassemia or Sickle Cell patients.

Dietary substances

A performance study was completed to investigate the interference of dietary substances on the OC Light dipstick and Alfa Instant View device (predicate). Aqueous extracts of raw broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip, and turnip were added to the test device to determine if vegetable extracts cross react with the test. The extracts were prepared by homogenizing raw vegetable in a food processor and then subsequently centrifuging the extract to separate the solid and liquid phases. Dietary iron and Vitamin C supplements and horseradish peroxidase were also tested for corss reactivity. The dietary substance extracts were added to normal stool extracts at both 0 and 50 ng/mL human hemoglobin (hHb). The OC Light dipstick and predicate device produce acceptable results for the interference of dietary substances study. All of the 0 ng/mL Hb samples spiked with an interfering substance produced negative results. All of the 50 ng/mL Hb samples spiked with an interfering substance were positive on the OC Light and predicate devices.

Toilet water

Toilet water was tested with the presence of various cleaners, from enzymatic to chlorox based. Toilet water was added to normal stool extracts at both 0 and 50 ng/mL human hemoglobin (hHb). All of the 50 ng/mL Hb samples spiked with toilet water samples were positive on the OC Light and all the 0 ng/mL Hb samples spiked with toilet water continued to be negative on OC Light.

Contaminants

A residual concentration equal to 50 ng/mL of Hb that remains in the toilet water will produce a false positive result when introduced to the OC Light test. It is suggested to avoid contact of the feces specimen with the toilet water during the collection process. The specimen should be collected on clean paper or in a clean container for sampling.

f. Assay cut-off:

The cut-off for the Poly Stat OC Light FOB test is 50 ng/mL. The reproducibility data showed 78% of the samples tested positive at 50 ng/mL.

2. Comparison studies:

a. Method comparison with predicate device:

A Medical Technologist (professional user) tested the same set of extracted samples with the Poly stat OC Light FOB test and the Alfa Scientific test (predicate device). The number of positive and negative result for each level of spiked hemoglobin concentration is presented for both the test and predicate device. There was 99.9% (300/300) agreement between the results obtained from the predicate and test device.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

A. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.